UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

DATE: Jan. 9, 2020

SUBJECT: Science Review of registrant's submission, dated December 11, 2019, in response to EPA's 75-day deficiency letter, dated November 7, 2019. The deficiencies identified by the Agency relate to product performance data in support of label amendment to add sublabel B for Water Soluble Pouch (WSP) to the Master label of Metalarv S-PT Mosquito Growth Regulator Spherical Pellet (VBC-60554 WSP) (EPA Reg No. 73049-475). The product contains 4.25 % w/w of S-Methoprene as Active Ingredient, supplied from a registered Source. PRIA B680 Registration.

Decision Number:	547672
DP Number:	455528
Submission Number:	1038777
EPA Symbol Number:	73049-475
Active Ingredient Type:	Biochemical
PC Code:	105402
CAS Number:	65733-16-6
Tolerance/Exemption (AI):	40 CFR 180.1033
MRID Numbers:	509180-01

FROM: Clara Fuentes, Ph.D. Entomologist
Risk Assessment Branch
Biopesticides & Pollution Prevention Division (7511P)

CLARA FUENTES Digitally signed by CLARA FUENTES Date: 2020.01.09 16:49:31 -05'00'

THROUGH: Mary Rust, Acting Risk Assessment Process Leader
Risk Assessment Branch
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MARY RUST 2020.01.09 16:55:24 -05'00'

TO: Menyon Adams, Risk Manager
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

RAB is requested to eview product performance data in MRID 509180-01 and label amendment, submitted in response to registrant's response to deficiencies, identified by the Agency in a 75-day letter, dated November 7, 2019, concerning proposed application rates and extended residual efficacy of VBC-60554 WSP against mosquito larvae in catch basins.

EXECUTIVE SUMMARY

Valent BioSciences LLC (VBC) is submitting product performance data (MRID 509180-01) in support of a label amendment to add a sublabel for a Water Soluble Pouch (VBC-60554 WSP) to the Master label of end-use product, Metalarv S-PT Mosquito Growth Regulator Spherical Pellet (VBC-60215) (EPA Reg No. 73049-475). The proposed label amendment will extend the residual performance claim of VBC-60554 WSP for up to 105 days against *Culex* mosquitoes in catch basins. The End-Use Product, Metalarv S-PT Mosquito Growth Regulator Spherical Pellet (VBC-60215), containing 4.25 % w/w of the active ingredient S-methoprene, is formulated to release S-methoprene over time from a spherical pellet carrier. VBC-60215 is registered to prevent the emergence of adult floodwater mosquitoes such as *Aedes, Ochlerotatus*, and *Psorophora* spp., as well as adult standing water-mosquitoes such as *Anopheles, Culex, Culiseta, Coquillettidia*, and *Mansonia* spp. for up to 6 weeks (42 days) when the product is applied at floodwater sites and permanent water sites at rates ranging from 2.5 –5 lbs /Acre to 5- **10 lbs/ Acre**. These application rates are equivalent to 0.000057 lb / sq. ft. – 0.00011 lb/ sq.ft. to 0.00011 lb/ sq.ft. – **0.00023 lb/ sq.ft.**, respectively. The product, VBC-60554 WSP consists of water soluble pouches, each pouch containing 18 grams (0.040 lb) of MetaLarv S-PT (VBC-60215). The product, VBC-60554 WSP, is intended for control of *Culex* mosquitoes in catch basins, storm drains, and standing water sites at application rate of 1 pouch (18 g = 0.040 lb) / 200 sq. ft. This application rate is equivalent to **0.0002 lb / sq. ft.**, **which is equivalent to the highest rate of 10 lbs / Acre**, recommended for treatment of floodwater sites and permanent water sites with Metalarv S-PT Mosquito Growth Regulator Spherical Pellet (VBC-60215). The highest rate of application is recommended for control of mosquitoes in catch basins because the treatment includes the opening of the catch basin as well as the piping system associated with it.

SUMMARY OF SUBMITTED STUDY

MRID 509180-01 includes 2 separate studies showing performance of VBC-60554 WSP against larvae of *Culex pipiens* and *Culex quinquefasciatus* in catch basins treated at a rate of 1 pouch / 200 sq. ft. One study was a field test conducted on street catch basins naturally infested with *Culex pipiens*. The second study was conducted in simulated catch basins naturally infested with *Culex quinquefasciatus*. Both studies included control treatment and treatments with other products, VBC-60555 (Altasoid XR), and VBC 60553 (Metalary S-PT 5 gram WSP). All treatments in the field study were replicated 10 times, and all treatments in the simulated catch basin study were replicated 5 times. Street basins were monitored for density of larvae, live and dead pupae for 18 weeks post-treatment. Simulated catch basins were monitored for presence of pupae and density of exuviae (skeletal remains of mosquitoes) for 23 weeks post-treatment. Live pupae were collected and held for adult emergence on both studies on all sampling weeks. Number of emerged adults was divided by total number of isolated pupae to calculate percent adult emergence per sampling week. Weekly efficacy of the product was expressed as % Emergence Inhibition (% EI) by dividing percent adult emergence in the treated basin (T) by the percent adult emergence in untreated basin (C) multiplied by 100 and subtracted from 100: % EI = 100 – 100 (T/C). Average % EI of *Culex pipiens* larvae in street catch basins treated with 0.0002 lb / sq. ft. of VBC-60554 WSP was 92 % for up to 105 days post treatment. For simulated basins treated with 0.0002 lb / sq. ft. of VBC-60554 WSP, average % EI of *Culex quinquefasciatus* was 97% for up to 112 days post-treatment indicating effective treatment.

CONCLUSIONS, COMMENTS and RECOMMENDATIONS

- The registrant has adequately responded to the Agency's request for data on additional mosquito species other than *Culex* spp. in support of efficacy claim against mosquitoes in water drainage systems and catch basin sites.

- Species from the 3 representative genera, *Aedes, Anopheles* and *Culex*, are represented on the label and supported by product performance data. Label instructions break down product application per site and mosquito species inhabiting specific sites, which is acceptable. Product application rates differ by type of application site, and mosquito spp. inhabiting specific sites; these are specified in the Application Directions section of the label.

- Language in SUB-LABEL A: Metalarv S-PT Products NOT in Water Soluble Packaging, groups *Anopheles* and *Culex* spp. as standing water mosquitoes: "*Anopheles, Culex, Culiseta, Coquillettidia, and Mansonia spp (adult standing water mosquitoes)*" and *Aedes* spp. within the floodwater mosquito complex "*Aedes, Ochlerotatus, and Psorophora spp.*(adult floodwater mosquitoes)."

- Language on SUB-LABEL A: Metalarv S-PT Products NOT in Water Soluble Packaging, reads as follows:
"*MetaLarv S-PT Mosquito Growth Regulator Spherical Pellet (hereafter referred to as Metalarv S-PT) is formulated to release S-Methoprene insect growth regulator for up to 42 days. MetaLarv S-PT prevents the emergence of* ***Aedes****, Ochlerotatus, and Psorophora spp. (adult floodwater mosquitoes) and* ***Anopheles, Culex****, Culiseta, Coquillettidia, and Mansonia spp (adult standing water mosquitoes)"…"One application will control adult emergence for up to 42 days* (in APPLICATION DIRECTIONS).

- The registrant has amended language on SUB_LABEL B Metalarv S-PT Products in Water Soluble Packaging to specify rate of applications by site as follows: one application of 1 pouch /100 sq. ft. in drainage systems: catch basins and storm water sites (inhabited by *Culex* mosquitoes) will last 105 days. One application of 1 pouch / 100 sq. ft. in surface water: floodwater and standing water sites, such as ponds, lagoons, hollow tree holes, urns, rain barrels, livestock watering troughs, septic tanks, irrigation ditches, storm water retention areas, birth baths, fountains, pools, gutters, wheelbarrows, water gardens, discarded tires, roadside dishes, etc. (inhabited by floodwater mosquitoes) will last up to 42 days.

- In support of *Culex*-only claim on product label, the registrant provided the label of a similar product, Altasoid XR Extended Residual Briquets (EPA Reg. 2724-421, containing 2.1 % w/w S- Methoprene. The label of this referenced product states that the Altasoid XR Briquets prevents emergence of adult mosquitoes including ***Anopheles***, ***Culex***, *Culiseta, Mansonia, Coquillettidia*, as well as those of the floodwater mosquito complex, ***Aedes***, *Ochlerotatus and Psorophora* ,he application rates are by application site and mosquito species inhabiting those sites as follows:

- For the control of ***Aedes***, *Ochlerotatus and Psorophora* in floodwater **shallow depression sites** (≤ 2 feet of water) place 1 briquet / 200 sq. ft. For the control of ***Anopheles***, ***Culex***, *Culiseta,* place 1 briquet / 100 sq. ft. For control of *Mansonia* and *Coquillettidia* mosquitoes in cattail marshes and water hyacinth beds, place 1 briquet / 100 sq. ft.

- The currently amended language in SUB-LABEL B: Metalarv S-PT Products in Water Soluble Packaging is consistent with instructions in label for Altasoid XR Extended Residual Briquets (EPA Reg. 2724-421, containing 2.1 % w/w S- Methoprene. Instructions are given for the control of *Anopheles* and *Culex* in standing water sites while, application of the product to drainage areas, sewers and catch basins is for the control of *Culex* mosquitoes inhabiting those specific sites.

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- Lastly, the registrant has provided a satisfactory explanation for application of the highest rate for control of mosquitoes in catch basins, which takes into account treatment of the opening of each basin plus the surface area of treated water in the associated piping system.

cc: Clara Fuentes, Menyon Adams, BPPD Chron. File, IHAD/ARS, FT, PY-S: 01/09/2020